

**FAST FREEZE- menthol spray**  
**Natural Essentials Inc.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Drug Facts**

**Active ingredients**

Menthol 10%

**Purpose**

Cooling Pain Relief

**Uses**

Temporary relief of minor aches and pains of muscles and joints associated with:

- Simple backache
- Arthritis
- Strains
- Sprains

**Warnings**

- **For external use only**
- Flammable
- Keep away from excessive heat or open flame
- Avoid spraying in eyes
- Contents under pressure. Do not puncture or incinerate container. Do not store at temperature above 120°F (48°C)

**Do not use**

- With heating pad or device
- With ointments, creams, sprays or liniments
- On wounds, damaged skin or irritated skin

**Ask a doctor before use if you**

- Have sensitive skin
- Are pregnant or breastfeeding

**When using this product**

- Avoid contact with eyes or mucous membranes
- Do not bandage tightly

**Stop use and ask a doctor if**

- Condition worsens
- Symptoms persist for more than 7 days or clear up then reoccur again within a few days
- Irritation develops

**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

**Adults/Children 2 years and older:**

- Spray on the affected area not more than 3 to 4 times daily
- Shake well before use

**Children under 2 years old:** Consult a physician.

**Other information**

- Replace cap after use
- Store in a cool, dry place

**Inactive ingredients**

Aloe Barbadosis (Aloe Vera) Leaf Extract, Ilex Paraguariensis Leaf Extract, SDA-39c Alcohol, Tocopherol (Vitamin E) Acetate, Water

**Questions?**

Call 317-228-1144 or visit [www.Bell-Horn.com](http://www.Bell-Horn.com) or [www.fastfreeze.com](http://www.fastfreeze.com)

Principal Display Panel – Bottle Label

***FAST FREEZE***<sup>®</sup>

Naturally  
Cool

Pain Relieving

Continuous Spray

Helps to relieve

- Sore muscles
- Strains & sprains
- Joint pain

- .....
- Invigorating cooling menthol
  - Greaseless & stain-free
  - Natural ingredients include  
Vitamin E, Aloe & Ilex

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4 oz (118 mL)

**Drug Facts**

NDC 66902-015-44

**Active Ingredients**

Menthol 10%..... Cooling Pain Relief

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• Simple backache • Arthritis • Strains • Sprains**Warnings**• For external use only • Flammable • Keep away from excessive heat or open flame  
• Avoid spraying in eyes • Contents under pressure. Do not puncture or incinerate container.  
Do not store at temperature above 120°F (48°C)**Do not use** • With heating pad or device • With ointments, creams, sprays or liniments  
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• Do not bandage tightly**Stop use and ask a doctor if** • Condition worsens  
• Symptoms persist for more than 7 days or clear up then reoccur again within a few days  
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**Inactive ingredients** Aloe Barbadensis (Aloe Vera) Leaf Extract, Ilex Paraguariensis Leaf Extract, SDA-39c Alcohol, Tocopherol (Vitamin E) Acetate, Water**Questions?** Call 317-228-1144 or visit [www.Bell-Horn.com](http://www.Bell-Horn.com) or [www.fastfreeze.com](http://www.fastfreeze.com)MADE IN USA  
Manufactured for:  
DJO, LLC  
Vista, CA 92081  
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BH-6205 Rev B

**FAST FREEZE****Naturally Cool**  
Pain Relieving  
Continuous Spray

Helps to relieve

- Sore muscles
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- Invigorating, cooling menthol
- Greaseless & stain-free
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4 oz (118 mL)

**FAST FREEZE**

menthol spray

**Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66902-015
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	100 mg in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66902-015-27	1 g in 1 BOTTLE, PUMP		
2	NDC:66902-015-04	1 g in 1 BOTTLE, PUMP		
3	NDC:66902-015-44	1 g in 1 CAN		

4	NDC:66902-015-16	1 g in 1 BOTTLE, PUMP		
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## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/01/2013	

**Labeler** - Natural Essentials Inc. (947484713)

## Establishment

Name	Address	ID/FEI	Business Operations
Natural Essentials Inc.		947484713	MANUFACTURE(66902-015)

Revised: 12/2012

Natural Essentials Inc.